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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/863,786

05/23/2001

Ronnie Palmgren

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2351

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05/20/2004

AMERSHAM BIOSCIENCES
PATENT DEPARTMENT
800 CENTENNIAL AVENUE
PISCATAWAY, NJ 08855

EXAMINER

DAVIS, DEBORAH A

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 05/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/863,786	PALMGREN ET AL.	
	Examiner	Art Unit	
	Deborah A Davis	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5-23-01.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 7 recites the limitation "activated acid moiety" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 1-6 and 10-13 and 15-18 are rejected under 35 U.S.C. 102(a) as being anticipated by Keough et al (WO 00/43792).

Keough et al anticipates the instant invention by teaching a method of identifying a polypeptide by derivatizing the N-termini of one or more peptides with one or more acidic moieties having a pKas of less than about 2 when coupled with the polypeptide or peptide to provide one or more derivatized analytes. This method is analyzed by mass spectrometric techniques to provide a fragmentation pattern (summary). Such mass

Art Unit: 1641

spectral techniques include Electrospray Ionization (ESI) and Matrix Assisted Laser Desorption Mass Spectrometry (MALDI) (page 16, lines 16-35 and page 17, lines 15-30). The fragmentation pattern of the peptide is interpreted to sequence the polypeptide (page 7, lines 1-2). Thomas et al discloses coupling an acidic moiety reagent to the N-terminus of a cysteine-containing peptide, followed by oxidation to produce peptides containing two acidic moieties (sulfonic acids). The preferred acidic moieties are 2-sulfoacetyl, 2-sulfobenzoyl and 3-sulfopropionyl moieties (page 9, lines 1-15). These preferred acidic moieties are sulfonyls coupled to an ester moiety such as sulfosuccinic anhydride, and 2-sulfobenzoic acid cyclic anhydride and others (page 9, lines 1-30). The peptides are accurately determined using software that accepts mass spectral fragmentation data (page 18, lines 15-22). The polypeptide can be obtained by enzymatic digestion using trypsin, or chymotrypsin (page 8, lines 3-12). Keough et al also teaches kits with one or more acidic moiety reagents having P_{Kas} less than about 2 when coupled with the polypeptide or one or more peptides. One or more buffer systems used to facilitate derivatization of peptides are also included in the kit of the present invention wherein buffer systems used is dependent on the acidic moiety reagent included (page 23, lines 1-35). Keough et al is silent with respect to the half-life of the acid reagent not being less than 10 minutes, however, it is the Examiner's position that this teaching is inherent to what the instant reference teaches. Keough et al teaches the acid reagents utilized in the instant invention, therefore these reagents will inherently exhibit a half-life in aqueous solution of not less than 10 minutes.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 13-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Little et al (USP6,322,970).

Little et al anticipates the instant reference by teaching reagents comprising a sulfonyl moiety coupled to an ester moiety and a reagent selected from the group consisting of 3-sulfopropionic N-hydroxysuccinimide esters (column 59, lines 65-67).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 7-9 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keough et al in view of Little et al (USP#6,322,970).

The teachings of Keough et al are set forth above and differ from the instant claims by not disclosing a sulfonyl group being coupled to a particular ester such as N-hydroxysuccinimide (NHS) ester.

However, Little et al discloses a process for determining the identity of a target polypeptide using mass spectroscopy (abstract). Little et al discloses that target

Art Unit: 1641

polypeptides can be captured by conjugation to a solid support by immobilizing. The conjugation can be mediated through a linker such as a sulfo-N-hydroxysuccinimide (NHS) ester that facilitates conjugation of the polypeptide through its amino terminus. (column 55, lines 40-66, column 56, lines 1-20 and column 59, lines 30-66 and column 60, lines 1-26) Claim 12 recites a step of protecting lysine residues prior to derivatizing. Little et al discloses that the termini of a target polypeptide are more reactive than the amino acid side groups and therefore the amino acid residues should be blocked prior to performing the reaction of interest (column 60, lines 27-50).

It would have been obvious to one of ordinary skill in the art to modify the reference of Keough et al to couple an N-hydroxysuccinimide (NHS) ester to a sulfonyl group taught by Little et al to facilitate conjugation of peptides to a solid support which has the advantage of being manipulated so that reagents and undesirable reaction products can be washed from the remaining immobilized polypeptide, which can then be cleaved from the solid support and analyzed by mass spectrometry (column 60, lines 17-27).

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

A. Sepetov et al. Teaches peptide sequencing using mass spectrometry (USP#5,470,753).

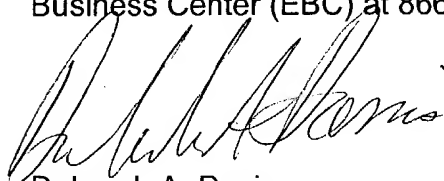
Art Unit: 1641

B. Benkovic et al teaches a method for determining the molecular weights of femtomole of peptides using time-of-flight secondary ion mass spectrometry (USP#5,834,195).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (571) 272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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05/15/04